

**SUMMARY OF SAFETY AND EFFECTIVENESS**

K980461  
MAR - 4 1998

**SPECTRUM DESIGNS CLEFT CHIN IMPLANT  
510K SUMMARY**

**1. Submitter's Data**

Spectrum Designs Inc.  
5921 C Matthews Street  
Goleta, CA 93117

Contact Person: Jim Dishman  
Telephone: 805 681 4899  
Date Prepared: January 17, 1998

**2. Device Name, Classification**

Name: Spectrum Designs Cleft Chin Implant  
FDA Classification: Class II, Prosthesis, Chin, Internal, Classification Number  
79FWP, 21 CFR 879.3550

**3. Identification of Substantially Equivalent Devices**

Spectrum Designs Cleft Chin Implant

**4. Device Description**

The Spectrum Designs Cleft Chin Implant is manufactured from solid silicone elastomer which is implanted in a pocket created by the surgeon, either intraorally or extraorally, in the mandibular region of the facial skeleton.

**5. Indications for Use**

The Spectrum Designs Cleft Chin Implant is a silicone facial implant, designed to augment or reconstruct the mandibular or chin area of the face.

**6. Contraindications for Use**

Contraindications for routine aesthetic surgery include the presence of infection anywhere in the body and in particular, in the region in which the device will be implanted.

**7. Warnings, Precautions**

Possible complications include:

- Displacement of the implant may occur, especially from dissection of too large a pocket.
- Errors in positioning the implant may result in patient dissatisfaction
- Tissue necrosis may result in extrusion of the implant. This can occur as a result of such factors as the pocket created being too small, use of too large an implant, or when soft tissues are inadequate to maintain coverage over the prosthesis
- Resorption of the underlying bone may occur with use of the implant.
- Fibrous tissue encapsulation can occur around any implant, with subsequent increased firmness, possible displacement, and/or pains.
- Complications from this or any similar surgery may include infection, neural damage, hematoma, poor wound healing, patient intolerance to foreign body implantation, and other similar complications.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Jim Dishman  
Spectrum Designs, Incorporated  
5921-C Matthews Street  
Goleta, California 93117

MAR - 4 1998

Re: K980461  
Trade Name: Spectrum Designs Cleft Chin Implant  
Regulatory Class: II  
Product Code: FWP  
Dated: January 17, 1999  
Received: February 5, 1998

Dear Mr. Dishman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

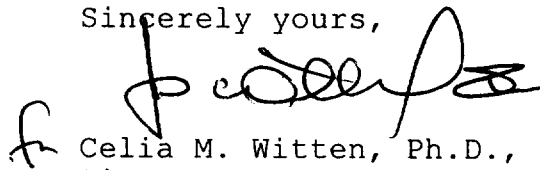
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Dishman

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', is written over the typed name.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Include the following "Indications For Use" page that contains the applicant's name, name of the device and the intended use of the device. The information, data and labeling claims in the entire 510(k) submission must support and agree with the "indications for use" statement.

\*For a new submission, do NOT fill in the 510(k) number blank.

### INDICATIONS FOR USE

Applicant: Spectrum Designs, Inc.

510(k) Number (if known): K980461 \*

Device Name: Spectrum Designs Cleft Chin Implant

#### Indications For Use

The Spectrum Designs Cleft Chin Implant is intended to augment or reconstruct the mandibular or chin area of the face.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K980461

Prescription Use X  
Per 21 CFR 801.109

or Over-the counter